IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

H. LUNDBECK A/S, TAKEDA PHARMACEUTICAL COMPANY LTD., TAKEDA PHARMACEUTICALS U.S.A., INC., TAKEDA PHARMACEUTICALS INTERNATIONAL AG and TAKEDA PHARMACEUTICALS AMERICA, INC.,	)	
Plaintiffs,	)	C.A. No. 18-88-LPS CONSOLIDATED
v.	)	**REDACTED - PUBLIC VERSION**
APOTEX INC., et al.,	)	
Defendants.	)	

LETTER TO THE HONORABLE LEONARD P. STARK FROM MEGAN E. DELLINGER REGARDING DISCOVERY DISPUTE WITH SIGMAPHARM

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mdellinger@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

George F. Pappas
Einar Stole
Christopher N. Sipes
Brianne Bharkhda
Priscilla G. Dodson
Alaina Whitt
Allison Schmitt
COVINGTON & BURLING LLP
One CityCenter
850 Tenth Street NW
Washington, DC 20001-4956
(202) 662-6000

Yiye Fu
COVINGTON & BURLING LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065-1418
(650) 632-4700

Original Filing Date: December 12, 2018
Redacted Filing Date: December 19, 2018

Dear Chief Judge Stark:

Paragraph 8.c of the Scheduling Order in this case required Defendant Sigmapharm Laboratories, LLC ("Sigmapharm") to produce its active ingredient Drug Master File ("DMF") No. 031898 to Plaintiffs.[1] The version of the DMF Sigmapharm produced contained extensive redactions, including stripping the DMF of all information [redacted]. Sigmapharm contends that [redacted] and, thus, noninfringing. Yet, Sigmapharm has refused to produce, even to Outside Counsel, an unredacted version of the DMF, arguing that its redactions are proper on relevance grounds and as a mechanism to protect Sigmapharm's purported "trade secrets." As explained below, both arguments are without merit. Indeed, if Sigmapharm's actions are permitted, it will open the door for accused infringers to withhold evidence of their infringement on the ground that it is a trade secret and thus undiscoverable.

In an effort to resolve this dispute without Court intervention, Plaintiffs offered to limit disclosure of the unredacted version of DMF No. 031898 only to Plaintiffs' Outside Counsel and outside experts. Sigmapharm refused, even though in-house counsel would not have access. Plaintiffs remain willing to abide by these restrictions, which go above and beyond the robust protections provided by the Protective Order. Accordingly, Plaintiffs ask that the Court order Sigmapharm to produce an unredacted version of DMF No. 031898, including all documents listed in Exhibit 1, for disclosure to Plaintiffs' Outside Counsel and outside experts. At the very least, Plaintiffs request that the Court order Sigmapharm to produce an unredacted version of its DMF to Outside Counsel. There is no reasonable argument that disclosure of this information to Outside Counsel poses a competitive risk to Sigmapharm.

I. The Redacted Material Is Discoverable and Relevant.

[redacted] is at the heart of the infringement dispute in this case. The claims asserted against Sigmapharm are directed to [redacted].[2] Sigmapharm's noninfringement arguments rest on its assertion that [redacted], and not [redacted]. The material Sigmapharm relies on for its noninfringement arguments and which it has redacted is relevant to the issue of infringement in this case, as it is likely to shed light on the nature and characteristics of [redacted]. *See In re Gabapentin Patent Litig.*, 393 F. Supp. 2d 278, 287 (D.N.J. 2005) ("Here, Teva's optimized manufacturing process for gabapentin is recorded in the Drug Master File that it filed with the FDA. The manufacturing process and testing conducted on samples made from that process are clearly relevant to the infringement inquiry."). The Court recognized the discoverability and relevance of Defendants' drug substance DMFs, when it ordered production of such documents by September 14. *See* D.I. 31 ¶ 8.c.; *see also* Ex. 7 at, *e.g.*, 27:21-29:8.

---

[1] Examples of the redactions to Sigmapharm's documents are attached as Exs. 2-6. These exhibits are merely a small sample of the extensive redactions that appear throughout the DMF.

[2] U.S. Patent 7,144,884: claims 1-12 and 17; U.S. Patent 8,476,279: claims 1-5 and 12-15; U.S. Patent 8,722,684: claims 1, 2, 3, and 5; U.S. Patent 8,969,355: claims 1, 2, 4, 5, and 7; U.S. Patent 9,227,946: claims 1, 2, 4, and 5; and U.S. Patent 9,861,630: claims 1-7.

Sigmapharm's obligations to produce discoverable documents that may bear on the issue of infringement are not negated by production of samples of its API and ANDA Product. On the contrary, discovery of Sigmapharm's unredacted DMF is of particular importance in this case. Although Sigmapharm has produced API and ANDA Product samples, Sigmapharm has indicated its intent to argue that [redacted] *See* Ex. 8.

Even if Sigmapharm could show that the redacted information is irrelevant, "a party may not redact information that it unilaterally deems sensitive, embarrassing, or irrelevant." *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, C.A. No. 13-2108-RGA, 2016 WL 720977, at *6 (D. Del. Feb. 23, 2016); *see also* Transcript of Telephone Conference at 27-28, *Morphosys AG v. Janssen Biotech, Inc.* C.A. No. 16-221-LPS-CJB (D. Del. Oct. 14, 2016), D.I. 59 (Ex. 9) (rejecting proposal for redaction provision in protective order). The Protective Order in this case permits redactions only for privilege and to comply with applicable personal or data privacy laws. Neither of these are applicable here. D.I. 132 ¶ 20. In fact, this Court rejected Defendants' request for a provision allowing the clawback of purportedly irrelevant documents. D.I. 106.

Judge Robinson previously rejected a similar attempt by Sigmapharm to shield [redacted] from discovery on relevance grounds. In *Forest Laboratories LLC v. Sigmapharm Laboratories LLC*, C.A. No. 14-1119-SLR/SRF (D. Del. 2014), Sigmapharm asserted that its product used noninfringing amorphous material, and plaintiffs sought disclosure of information regarding the manufacturing process of Sigmapharm's API to its outside experts. Judge Robinson concluded that the manufacturing information sought was relevant and denied Sigmapharm's request to prevent disclosure of Sigmapharm's information to outside experts. *Id.* at ¶ 4. ("An issue that not atypically arises in such polymorph cases is whether the amorphous form of the accused generic converts to the crystalline form and how robust the process for preparing the generic product is in this regard.") (Ex. 10).[4]

II. Sigmapharm Cannot Justify Its Redactions By Claiming That They Are Trade Secrets.

Sigmapharm also claims that it is entitled to redact the [redacted] information at issue because it constitutes a "trade secret" that, in Sigmapharm's view, cannot be adequately protected by the provisions of the Protective Order.[5] Plaintiffs dispute that the redacted information constitutes a

[3] Sigmapharm has not produced any evidence that the [redacted]

[4] Plaintiffs understand that Sigmapharm is attempting this tactic yet again, seeking to prevent discovery related to [redacted] in another pending dispute before this Court. *Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.*, C.A. No. 17-374-LPS (D. Del.) (teleconference held Nov. 30, 2018).

[5] Paragraph 41 of the Protective Order explains that "no information may be withheld from discovery on the ground that the material to be disclosed requires protection greater than that afforded by this Protective Order unless the party claiming a need for greater protection moves for an order providing such special protection pursuant to Federal Rule of Civil Procedure 26(c)." D.I. 132 ¶ 41. Sigmapharm has made no such motion. More generally, Sigmapharm bears the burden to (continued…)

trade secret. But even if it is, Sigmapharm's assertion that its information is so secret that it cannot be adequately protected under the Protective Order, or by limited production to Plaintiffs' Outside Counsel or outside experts, is without merit. Trade secrets expressly fall within the "Confidential Information" and "Competitively Sensitive Confidential Information" categories under the Protective Order. *See* D.I. 132 ¶¶ 1, 14. The Protective Order sets forth a host of provisions designed to protect this information from improper use. *See, e.g.*, D.I. 132 ¶¶ 5, 7, Ex. B. The parties debated the terms of the Protective Order at length. D.I. 98; D.I. 100; D.I. 101; D.I. 102; D.I. 103; D.I. 104; D.I. 124; D.I. 125. Sigmapharm never raised with Plaintiffs or the Court a concern that the Protective Order was inadequate to protect trade secret information. Rather, Defendants, including Sigmapharm, argued to the Court that the "Competitively Sensitive Confidential Information" category of the Protective Order was intended specifically to protect "portions of Drug Master Files containing trade secret information." D.I. 132 ¶ 14; D.I. 124.

Plaintiffs have further agreed that the unredacted DMF, if produced, will only be accessible to Outside Counsel and outside experts—not in-house counsel or competitive decision makers. Numerous courts, including the District of Delaware, have previously required production of trade secrets on such terms. *See Safe Flight Instrument Corp. v. Sundstrand Data Control Inc.*, 682 F. Supp. 20, 22 (D. Del. 1988) (collecting cases in which outside counsel and outside experts were permitted access to highly confidential technical information such as trade secrets); *Medtronic Ave, Inc. v. Advanced Cardiovascular Sys., Inc.*, C.A. 98-80-SLR, 2004 WL 115594, at *3 ("Medtronic's interests will not be in jeopardy by providing the redacted information to Medtronic's legal counsel and independent experts"); *Tailored Lighting, Inc. v. Osram Sylvania Prods., Inc.*, 236 F.R.D. 146, 148 (W.D.N.Y. 2006) ("Indeed, in cases involving the disclosure of trade secrets, courts often issue protective orders limiting access to the most sensitive information to counsel and their experts.").[6]

Access for outside experts is necessary because such individuals have the expertise to analyze the information and explain its significance to the Court at trial. The Protective Order contemplates advanced disclosure of all outside experts and provides an opportunity to object. D.I. 132 ¶ 5. Outside experts must agree to protect disclosed information, and not to use the information for any purpose other than this case. D.I. 132 Ex. B. Sigmapharm has not articulated a concrete reason why Plaintiffs' outside experts, many of whom have already been disclosed, pose a risk not accounted for by the provisions of the Protective Order. *See Forest*, C.A. No. 14-1119-SLR/SRF, D.I. 179, at ¶ 3 (Ex. 10).

Therefore, Plaintiffs request that the Court order Sigmapharm to produce an unredacted version of DMF No. 031898, including all documents listed in Exhibit 1, for disclosure to Plaintiffs' Outside Counsel and outside experts.

---

show that disclosure of this information should be precluded. *See Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994); *Medtronic*, 2004 WL 115594, at *2-3. It cannot meet this burden.

[6] To the extent that Sigmapharm seeks to rely on *Supernus Pharms., Inc. v. Actavis, Inc.*, C.A. No. 13-cv-4740-RMB-JS, at 12-13 (D.N.J. Sept. 15, 2015), D.I. 149 (Ex. 11), that case is inapposite here. That decision addresses disclosure of certain technical information to a proposed in-house technical advisor, which is not contemplated or requested here.

Respectfully,

/s/ Megan E. Dellinger

Megan E. Dellinger (#5739)

MED/bac
Attachments

cc: All Counsel of Record (via electronic mail; w/attachments)